Radioembolisation with yttrium–90 microspheres versus sorafenib for treatment of advanced hepatocellular carcinoma (SARAH): study protocol for a randomised controlled trial

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Résumé en anglais	**BACKGROUND:** Untreated advanced hepatocellular carcinoma (HCC) is linked to poor prognosis. While sorafenib is the current recommended treatment for advanced HCC, radioembolisation (RE; also called selective internal radiation therapy or SIRT) with yttrium-90 microspheres has shown efficacy in cohort studies. However, there are no head-to-head trials comparing radiation therapy with yttrium-90 microspheres and sorafenib in advanced HCC. The SARAH trial has been designed to compare the efficacy and safety of sorafenib therapy and RE using yttrium-90 resin microspheres (SIR-Spheres™; Sirtex Medical Limited, North Sydney, Australia) in patients with advanced HCC. Quality of life (QoL) and cost-effectiveness will also be compared between therapies. **METHODS/DESIGN:** SARAH is a prospective, randomised, controlled, open-label, multicentre trial comparing the efficacy of RE with sorafenib in the treatment of patients with advanced HCC. The trial aims to recruit adults with a life expectancy of >3 months, Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1, and: advanced HCC according to the Barcelona criteria (stage C) or recurrent HCC after surgical or thermoablative treatment who are not eligible for surgical resection, liver transplantation or thermal ablation; or two rounds of failed chemoembolisation. Patients will be randomised 1:1 to receive either RE or sorafenib 400 mg twice daily. All patients will be monitored for between 12 and 48 months following start of treatment. The primary endpoint of the SARAH trial is overall survival (OS). Secondary endpoints include: adverse events, progression-free survival at 6 months; tumour response rate; general or liver disease-specific QoL scores; and cost of each treatment strategy. Assuming an increase in median OS of 4 months with RE versus sorafenib therapy, randomising at least 400 patients (200 in each treatment arm) will be sufficient for 80% power and a bilateral alpha risk of 5%; therefore, 440 patients will be enrolled to allow for 10% loss of patients due to ineligibility. **DISCUSSION:** The SARAH trial is the first randomised head-to-head study to compare RE with sorafenib in advanced HCC, and will establish the potential role of RE in HCC treatment guidelines. **TRIAL REGISTRATION:** ClinicalTrials.gov identifier NCT01482442, first received 28 November 2011.
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